InPenTM User Experience

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The purpose of this study is the evaluation of InPen* with InPen* 2.0 app and Guardian* 4 system in adult patients with type 1 diabetes for the design of a future study.

Ethical review	Not approved
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON51696

Source
ToetsingOnline

Brief title
InPenTM User Experience

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Type 1 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: CGM (Continuous Glucose measurement), lnPen Diabetes Management App Guardian TM 4 system, Type 1 diabetes

Outcome measures

Primary outcome

N/A only descriptive endpoints for this study

Secondary outcome

N/A only descriptive endpoints for this study

Study description

Background summary

In patients with insulin dependent diabetes mellitus, glycemic control is influenced by numerous factors, such as insulin dosage, insulin absorption, timing, physiological/ lifestyle factors such as exercise, food intake, sleep, hormones and illness. These factors may contribute to significant variability in insulin requirements, which makes self-management of diabetes challenging. For people with diabetes who take insulin, missing an insulin dose may be a frequent occurrence. Until recently, there has been no objective way to know in patients on MDI therapy whether they have actually taken a dose. Therefore, clinicians rely on patient self-reports of insulin administration and must make changes in the insulin regimen with the presumption that the patient is taking their insulin as prescribed. This presumption may lead to over or under treatment, particularly if non-adherence is frequent. Recently, using novel Bluetooth-enabled insulin pen cap technology, non-adherence to insulin in patients with type 1 diabetes and type 2 diabetes was recorded for 24% of bolus insulin administration and 36%of basal insulin administration.
CGM improves a patient*s ability to get rapid and accurate glucose readings, however patients are still required to make hundreds of decisions a day with little guidance on what to eat, what to dose, when to dose, and how to manage activities such as exercise.
The InPen system integrated with real-time CGM (rtCGM) will provide the patient with intelligent automation, detection, insights, and recommendations that will enable them to make informed diabetes management decisions.

Study objective

The purpose of this study is the evaluation of InPen* with InPen* 2.0 app and Guardian* 4 system in adult patients with type 1 diabetes for the design of a future study.

Study design

This study is a multi-center, single arm, pilot study in adult subjects with type 1 diabetes treated with MDI (basal and bolus) therapy.
The total study duration will be approximately 10 weeks long for each subject.
The study consists of a run-in (phase 1) and study phases 2, 3 and 4

Intervention

Phase 1:
Enrollment (Visit 1) and Screening/Start Run-in (baseline/Visit 2) The purpose of the run-in phase is to collect data for two weeks while subjects are on their current MDI therapy. Blinded CGM will be utilized to collect the baseline CGM data. Baseline Hba1c will also be collected. Subjects will use the devices below for blinded CGM:
- Guardian* 4 Sensor
- Guardian* Link 3 transmitter

Phase 2 (Visit 3):
All subjects will utilize a smart bolus insulin pen injector (InPen*) and app with dose calculator (InPen* 2.0 app), and will continue their own self-monitoring of blood glucose (SMBG), intermittent scanning CGM (iscCGM) or real-time CGM (rtCGM) for two weeks.

Phase 3 (Visit 4):
Subjects will have an on-site or remote follow-up visit after Phase 2 (4 weeks from start/baseline). Subjects will continue on the InPen and InPen app for another two weeks incorporating HCP recommendations during the follow-up visit. Blinded CGM will be utilized for all subjects.

Phase 4 (Visit 5):
After four weeks of study phase, HbA1c will be collected, all subjects will stop their own iscCGM or rtCGM and will use the devices below (Visit 5):
- InPen* and InPen* 2.0 app
- Guardian* 4 system
o Guardian* 4 sensor
o Guardian* 4 transmitter
o Guardian* Clinical app

After two weeks on the system subjects will connect with the study center for an office or remote visit (Visit 6).

All subjects will utilize the InPen* system for four weeks and then exit from the study (Visit 7). At the study exit at Visit 7, HbA1c is collected.

Study burden and risks

The data collected in this pilot study has the potential to facilitate the development and availability of improved Medtronic devices that may provide significant benefits to patients in the future. In light of this, we believe that the overall future potential benefits to the general population of patients with diabetes outweigh any risk to subjects who choose to participate in the investigation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Inclusion Criteria:
1. Subject is aged 18-75 years at time of screening
2. Subject is on MDI therapy (defined as >= 3 insulin injections per day and on a basal/bolus regimen) >=1 year prior to screening
3. Subject has a clinical diagnosis of type 1 diabetes for 1 year prior to

screening
4. Subject has a Glycosylated hemoglobin (HbA1c) less than 12% as assessed by local lab or capillary blood testing <15 days prior to screening or at time of screening visit
5. Subject is on MDI therapy with
a. SMBG,
b. Real-Time Continuous Glucose Monitoring (rtCGM), or
c. Intermittent Scanning CGM (iscCGM)
6. Subject is willing to upload data from a BG meter, must have internet access and a compatible computer system that meets the requirements for uploading data at home.
7. Subject is willing and able to sign and date informed consent, comply with all study procedures, and wear all study devices, as required during the study.
8. Subject is willing to take or switch to one of the InPen-compatible insulin types, as per IFU

Exclusion criteria

1. Women of child-bearing potential who have a positive pregnancy test at screening or plan to become pregnant during the course of the study.
2. Women who are breastfeeding.
3. Subject has any unresolved adverse skin conditions in the area of sensor placement (e.g. psoriasis, dermatitis herpetiformis, rash, Staphylococcus infection).
4. Subject is actively participating in an investigational study (drug or device) wherein he/she has received treatment from an investigational study drug or device in the last 2 weeks before enrollment into this study, as per investigator judgment.
5. Subject is currently abusing illicit drugs, marijuana, alcohol or prescription drugs (other than nicotine), per investigator judgment.
6. Subject has any other disease or condition that may preclude the patient from participating in the study, per investigator judgment.
7. Subject is legally incompetent, illiterate or vulnerable person.
8. Research staff involved with executing the study.

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	InPen 2.0 app and Guardian 4 system
Registration:	No

Ethics review

Not approved

Date:	09-02-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05029271

Register	ID
CCMO	NL82648.078.22